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10/500,391	09/09/2004	Sanford Reich	642P002-US	9014

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Nields & Lemack
176 E. Main Street
Suite #5
Westboro, MA 01581

EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,391	REICH ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 17-26* is/are pending in the application.

4a) Of the above claim(s) *18-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,17,25,26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 2 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims.

Election/Restrictions

2. Newly submitted claims 18-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 18-24 are directed to a system comprising microprocessor executable instructions which are a feature of the examined invention. However the instructions comprise method steps for a method of regularly monitoring cerebrospinal fluid shunt flow resistance that are considered herein to be a separate invention that would have prompted a restriction requirement were the claims presented originally with the examined claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 26 recites the limitation "the supine mode" in line 4. There is insufficient antecedent basis for this limitation in the claim. Claim 26 also recites the limitation "the shunt"

repeatedly throughout the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 17, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen et al (U.S. Patent No. 6,383,160) in view of Cowan, Jr. et al (U.S. Patent No. 6,585,677).

With respect to **claim 1:** Madsen teaches a system for regulating the flow of cerebrospinal fluid (hereafter, “CSF”) from the brain of an individual comprising an implantable controller in the form of anti-siphon shunt valve 80 adapted to be in fluid communication with said CSF and having first and second drainage paths 86 and 88, respectively. Madsen teaches a system for

non-invasively monitoring the operation and performance of an implanted cerebrospinal shunting system comprising an implantable controller in the form of anti-siphon shunt valve 80. The controller further comprises an inclination sensor in the form of orientation sensor 104, a pressure sensor in the form of fluid sensor 102. Madsen teaches an embedded microprocessor in the form of controller 106, which will hereafter be referred to as “control 106” to avoid confusion with controller 80. The embedded microprocessor 106 is capable of reading the inclination sensor 104 and pressure sensor 102 inasmuch as their data points are both inputs to the processor. The microprocessor 106 transmits readings from the sensors in the form of signals to actuator 108 but does not transmit them using a wireless transceiver. The controller 80 taught by Madsen necessarily comprises a memory element associated with said microprocessor 106, as the microprocessor is programmable and must store data at least temporarily from fluid sensor 102 before converting the data to a signal to send to actuator 108. The memory element associated with microprocessor 106 is necessarily adapted to store at least one diagnostic algorithm inasmuch as the microprocessor itself is programmable and converts data from various inputs into signals for said actuator. (Col. 7, lines 6-21) The microprocessor is also considered herein to be adapted to perform at least one diagnostic test in conjunction with the controller because the processor 106 is programmable and because it receives data from the controller via pressure sensor 102.

Madsen teaches that the system comprises control 106 that can be external to the controller 80 but does not teach an external programmer with wireless capability or a wireless transceiver capable of communicating with an external programmer. Cowan teaches a wireless transceiver in the form of transmitter 64 within the instant controller that is operable to receive and emit or transmit information and is capable of communicating with an external programmer in the form of a computing device external to the patient (Col. 6, lines 5-15). An embedded

microprocessor within diagnostic unit 60 is housed within controller 24 and is thus embedded, capable of reading signals from said valve-gauge assembly which includes said inclination sensor and said pressure sensor in the form of said pressure gauge and transmitting, using said wireless transceiver 64, said readings from said sensors (Col. 5, lines 54-63, Col. 6, lines 3-6). Cowan teaches said external programmer having wireless capability, said programmer capable of wireless communication with said controller 24 via a receiver proximal to the patient and transmitter 64. (Fig. 1, Col. 6, lines 3-8) Since the devices of Madsen and Cowan seek to solve a similar problem in the art (i.e. monitor the drainage of cerebrospinal fluid in a patient and respond to prevent under- or over-drainage using external controls that communicate with an internal microprocessor), it would be obvious to one of ordinary skill in the art to modify the system of Madsen so as to instead comprise an external programmer with wireless capability that is capable of wireless communication with the instant controller as taught by Cowan with a reasonable expectation of success to monitor the progress of the CSF drainage treatment process. The device of the combined teaching of Madsen and Cowan also renders the limitation “a wireless transceiver capable of communicating with an external programmer” obvious. The combined teaching of Madsen and Cowan also renders the limitation "said programmer capable of wireless communication with said controller" obvious. The controller 80 is a multimode drainage system in which a first mode (first drainage path 86) is a low resistance supine flow path inasmuch as Madsen teaches that this is a path of least resistance through which CSF flows when the patient is recumbent, i.e. supine. (Col. 6, lines 37-43) A second mode of the multimode system of Madsen is a second variable upright path 88 inasmuch as Madsen teaches that when the patient stands up (or sits up), the anti-siphon valve 10 exhibits a high fluid flow resistance that is greater than the resistance of high-resistance valve 90, thus forcing valve 90 open to allow drainage of fluid through second pathway 88 to outlet 94. (Col. 6, lines

43-52) The selection of said mode is controlled by the controller inasmuch as Madsen teaches that data provided from orientation sensor 104 as to whether the patient is recumbent or vertical is provided to controller 106, which sends signals to actuator 108 to adjust the adjustable barrier accordingly to provide optimal drainage conditions for the patient according to the inclination of the user, wherein sensor 104, control 106 and actuator 108 are integral to the controller 80. (Col. 6, lines 6-17)

Madsen teaches that the system comprises 106 that can be external to the controller 80 but does not teach an external programmer with wireless capability. Cowan teaches a wireless transceiver in the form of transmitter 64 within the instant controller that is operable to receive and emit or transmit information and is capable of communicating with an external programmer in the form of a computing device external to the patient (Col. 6, lines 5-15). An embedded microprocessor within diagnostic unit 60 is housed within controller 24 and is thus embedded, capable of reading signals from said valve-gauge assembly which includes said inclination sensor and said pressure sensor in the form of said pressure gauge and transmitting, using said wireless transceiver 64, said readings from said sensors (Col. 5, lines 54-63, Col. 6, lines 3-6). Cowan teaches said external programmer having wireless capability, said programmer capable of wireless communication with said controller 24 via a receiver proximal to the patient and transmitter 64. (Fig. 1, Col. 6, lines 3-8) Since the devices of Madsen and Cowan seek to solve a similar problem in the art (i.e. monitor the drainage of cerebrospinal fluid in a patient and respond to prevent under- or over-drainage using external controls that communicate with an internal microprocessor), it would be obvious to one of ordinary skill in the art to modify the system of Madsen so as to comprise an external programmer with wireless capability that is capable of wireless communication with the instant controller as taught by Cowan with a

reasonable expectation of success to monitor the progress of the CSF drainage treatment process.

With respect to **claim 2:** Madsen does not teach an external programmer wit h wireless capability. Controller 24 taught by Cowan can wirelessly transmit data and status responses to said programmer via transmitter 64 and diagnostic unit 60. However Cowan does not teach that said external programmer can wirelessly transmit data and commands to said implanted controller 24. However, since Cowan teaches that the external computing device can automatically diagnose malfunction or infection and/or pass data to a doctor, and teaches a wireless receiver for receiving signals from said transmitter to pass to said external programmer, and further teaches that the valve gauge assembly 52 is responsible for determining the amount of CSF drainage, it would be obvious to one of ordinary skill in the art to modify the system of the combined teaching of Cowan such that, once said diagnosis is made, the external programmer wirelessly transmits data and commands to said implanted controller 24 to begin a treatment process involving a proper amount of CSF drainage, as Cowan explicitly teaches that the valve-gauge assembly within the controller 24 is microprocessor-based, meaning the assembly can receive and process data.

With respect to **claim 17:** The controller 80 taught by Madsen necessarily comprises a memory element associated with said microprocessor 106, as the microprocessor is programmable and must store data at least temporarily from fluid sensor 102 before converting the data to a signal to send to actuator 108. The memory element associated with microprocessor 106 is necessarily adapted to store microprocessor-executable instructions inasmuch as the

microprocessor itself is programmable and converts data from various inputs into signals for said actuator. (Col. 7, lines 6-21)

With respect to **claim 25:** Madsen teaches a system for non-invasively monitoring the operation and performance of an implanted cerebrospinal shunting system comprising an implantable controller in the form of anti-siphon shunt valve 80. The controller further comprises an inclination sensor in the form of orientation sensor 104, a pressure sensor in the form of fluid sensor 102. Madsen teaches an embedded microprocessor in the form of controller 106, which will hereafter be referred to as "control 106" to avoid confusion with controller 80. The embedded microprocessor 106 is capable of reading the inclination sensor 104 and pressure sensor 102 inasmuch as their data points are both inputs to the processor. The microprocessor 106 transmits readings from the sensors in the form of signals to actuator 108 but does not transmit them using a wireless transceiver. The controller 80 taught by Madsen necessarily comprises a memory element associated with said microprocessor 106, as the microprocessor is programmable and must store data at least temporarily from fluid sensor 102 before converting the data to a signal to send to actuator 108. The memory element associated with microprocessor 106 is necessarily adapted to store at least one diagnostic algorithm inasmuch as the microprocessor itself is programmable and converts data from various inputs into signals for said actuator. (Col. 7, lines 6-21) The microprocessor is also considered herein to be adapted to perform at least one diagnostic test in conjunction with the controller because the processor 106 is programmable and because it receives data from the controller via pressure sensor 102.

Madsen teaches that the system comprises control 106 that can be external to the controller 80 but does not teach an external programmer with wireless capability or a wireless

transceiver capable of communicating with an external programmer. Cowan teaches a wireless transceiver in the form of transmitter 64 within the instant controller that is operable to receive and emit or transmit information and is capable of communicating with an external programmer in the form of a computing device external to the patient (Col. 6, lines 5-15). An embedded microprocessor within diagnostic unit 60 is housed within controller 24 and is thus embedded, capable of reading signals from said valve-gauge assembly which includes said inclination sensor and said pressure sensor in the form of said pressure gauge and transmitting, using said wireless transceiver 64, said readings from said sensors (Col. 5, lines 54-63, Col. 6, lines 3-6). Cowan teaches said external programmer having wireless capability, said programmer capable of wireless communication with said controller 24 via a receiver proximal to the patient and transmitter 64. (Fig. 1, Col. 6, lines 3-8) Since the devices of Madsen and Cowan seek to solve a similar problem in the art (i.e. monitor the drainage of cerebrospinal fluid in a patient and respond to prevent under- or over-drainage using external controls that communicate with an internal microprocessor), it would be obvious to one of ordinary skill in the art to modify the system of Madsen so as to instead comprise an external programmer with wireless capability that is capable of wireless communication with the instant controller as taught by Cowan with a reasonable expectation of success to monitor the progress of the CSF drainage treatment process. The device of the combined teaching of Madsen and Cowan also renders the limitation “a wireless transceiver capable of communicating with an external programmer” obvious. The combined teaching of Madsen and Cowan also renders the limitation "said programmer capable of wireless communication with said controller" obvious.

With respect to **claim 26:** The diagnostic test that the external programmer of the combined teaching of Madsen and Cowan is adapted to perform is the distal flow resistance of the shunt in

the supine mode from the pressure sensor to the distal end of the shunt. Examiner's position is based upon the fact that the system of the combined teaching of Madsen and Cowan meets all of the limitations of claim 26 as to an external programmer with a memory element associated therewith adapted to store at least one diagnostic algorithm, a pressure sensor, and a controller/shunt with a supine mode operatively connected to the controller/shunt. Therefore, since all of these elements are required to perform this diagnostic test, the system of the combined teaching of Madsen and Cowan renders the limitation " wherein said diagnostic test is selected from the group consisting of computation of the distal flow resistance of the shunt in the supine mode from the pressure sensor to the distal end of the shunt, computation of the supine flow rate, computation of the cranial compliance, computation of the proximal shunt flow resistance and regular monitoring of cerebrospinal fluid shunt flow resistance" obvious.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761